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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,669	03/22/2004	Tracy Gibbs	T8907.CON	1161

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EXAMINER	
MELLER, MICHAEL V	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/806,669	GIBBS, TRACY	
	Examiner	Art Unit	
	Michael V. Meller	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-67* is/are pending in the application.

4a) Of the above claim(s) *57-61 and 63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-56, 62, 64-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-62, drawn to a composition, classified in class 435, subclass various.

II. Claim 63, drawn to a method of using said composition, classified in class 424, subclass various.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially distinct process such as treating wounds.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: the many different enzymes claimed.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 36, 63 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with David Osbourne on 10/11/2005 a provisional election was made with traverse to prosecute the invention of Group I and sucrase as the additional enzyme, claims 1-62. Affirmation of this election must be made by applicant in replying to this Office action. Claim 63 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 57-61, 63 remain withdrawn from further consideration by the examiner as being drawn to non-elected inventions.

Applicant's election of Group I, claims 1-62 and the species sucrase in the reply filed on 4/19/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The restriction requirement is made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 36-56, 62, 64-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorsek or Breitbarth taken with Mochizuki et al., Fallon, Pabst or Prentice et al., CN 1096457, Williams et al or Pero, Krumhar et al., Farmer, or Sachetto, Shigeki et al. (Kimura et al.) and Slaga et al.

Gorsek (see table 1) and Breitbarth (see col. 5, under number 6) teach that the enzymes (protease, amylase, lipase and cellulase) are used in a pharmaceutical composition together and that calcium, magnesium, zinc, and manganese are also used. Gorsek shows specifically calcium ascorbate.

Mochizuki et al. (col. 2, lines 25-65), Fallon (experiment 3), Pabst (abstract) and Prentice et al. (col. 16, lines 10-25) all show that sucrase can also be used in such a

pharmaceutical composition along with the enzymes. Mochizuki also teaches that Aspergillus niger is a known source of such enzymes.

CN 1096457 (abstract), Williams et al. (col. 5, table) and Pero (col. 3, table) show that zinc gluconate is known to be used in a pharmaceutical composition with such enzymes.

Krumhar et al. (col. 12, lines 33-65), Farmer (col. 24, lines 5-10), and Sachetto (col. 4, lines 55-60) show that magnesium citrate is known to be used in pharmaceutical composition with such enzymes.

Slaga (col. 16, line 30) teaches that manganese gluconate is used in pharmaceutical composition with such enzymes.

Shigeki et al. (Kimura-col. 4, lines 20-27, col. 5, lines 20-30) shows that amylase can be derived from Aspergillus oryzae and used for pharmaceutical purposes.

It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Sussman,* 1943 C.D. 518; *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Applicant argues that the references each are used for different purposes but this is not well taken.

In the primary references, Gorsek and Breithbarth, the compositions are clearly used for pharmaceutical purposes. The other references are also used for pharmaceutical purposes.

The only references which do not deal directly with pharmaceuticals are Prentice and Mochizuki, but Prentice establishes that sucrases are commonly known carbohydrases like amylases and cellulases (see col. 16, lines 10-25) which are in Gorsek and Breithbarth and Mochizuki establishes that Aspergillus niger is well known to produce common enzymes such as the ones claimed, cellulose, protease, sucrase, amylase, etc. (see col. 2, lines 25-65). Thus, these two references were merely cited to show that it would have been well within the purview of the skilled artisan to use sucrase in addition to the already described enzymes (amylase, cellulose, protease and lipase) since sucrase was a well known carbohydrase like the other enzymes and that aspergillus niger is well known to produce the claimed enzymes. To use enzymes from aspergillus niger is simply the choice of the artisan in an effort to optimize the desired results.

Thus, the rejection is proper.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael V. Meller

Primary Examiner
Art Unit 1655

MVM

MICHAEL MELLER
PRIMARY EXAMINER